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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,658	09/13/2006	Satoshi Yoshida	07580.0007	4726

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EXAMINER	
ANDERSON, HEATHER L	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,658	YOSHIDA ET AL.	
	Examiner	Art Unit	
	Heather Anderson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/11/2005 and 09/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating conditions associated with high levels of follicle-stimulating hormone, does not reasonably provide enablement for preventing or remedying those conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that the claimed compound is useful as a therapeutic agent for treating conditions associated with high levels of follicle-stimulating hormone and/or reducing the risk thereof. However, the claims also encompass using the claimed compound to prevent or remedy these conditions, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "preventive" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such

disorders as conditions associated with high levels of follicle-stimulating hormone (which clearly is not recognized in the medical art as being a totally preventable condition). Also note that the term "remedy" means to "cure or correct," and perimenopause is not known to be a curable condition.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of ordinary skill in the art to prepare a pharmaceutical composition comprising *Cucurbita moschata*, *Carthamus tinctorius*, *Plantago Asiatica*, and *Lonicera japonica* which would function in a manner so as to prevent any and all conditions associated with high levels of follicle-stimulating hormone (including perimenopause).

It is suggested that the claims be appropriately amended so as to remove the terms "preventive" and "remedy" therefrom to overcome the above rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are rendered vague and indefinite because, as drafted, they appear to be a literal translation into English from a foreign document and use many idiomatic, unusual and non-clinical terms (recited throughout the instant claims). For example, the terms "climacteric disturbance," "ovarian hypofunction," and "testicular deficiency" should be amended to use the

more current medical terms of "perimenopause," "premature ovarian failure," and "primary hypogonadism," respectively. Furthermore, the term "indefinite complaint" is not a medically recognized condition at all, nor is it described in the specification adequately for a substitute term to be determined. It is recommended that claim 3 be cancelled in light of the degree of vagueness of this term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by either Yoshida et al. (JP 11-116498, AIPN translation provided) or Kojima et al. (US 5,882,672).

A composition comprising *Cucurbita moschata*, *Carthamus tinctorius*, *Plantago Asiatica*, and *Lonicera japonica* is claimed.

Yoshida et al. teach a composition comprising pumpkin seed and safflower and either *Plantago Asiatica* or *Lonicera japonica* or both (see, e.g., abstract and entire translated document). The particular species names for the pumpkin seed and safflower used are given in paragraph [0015]. The composition can also be a health food (paragraph [0021]). Although no patentable weight is given to the intended use of the instantly claimed composition (product), it is described in paragraph [0015] that the flowers of *Carthamus tinctorius* are used for the treatment of women's diseases, specifically menopause.

As readily admitted by Applicant on page 3, lines 19-24 of the instant specification, Kojima et al. teach a composition comprising Cucurbita seed, Plantago and Lonicera and at least one additional crude drug such as safflower (see, e.g., claim 1 and entire document). The particular species of each of the above herbals are given respectively on column 2, line 33; column 3, line 13; column 2, line 40 and column 2, line 48. Although no patentable weight is given to the intended use of the instantly claimed composition (product), it is noted that by Kojima et al. that safflower is used in the treatment of gynecological disorders and climacteric disturbance (column 3, lines 14-19).

It is further noted that upon administration of either of these two compositions, a preventive or remedial effect on the conditions in claims 2-12 would inherently occur.

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (JP 11-116498, AIPN translation provided) or Kojima et al. (US 5,882,672).

A composition comprising *Cucurbita moschata*, *Carthamus tinctorius*, *Plantago Asiatica*, and *Lonicera japonica* is claimed. Dependent claims include various uses and formulations of the composition.

Yoshida et al. beneficially teach a composition comprising pumpkin seed and safflower and either *Plantago Asiatica* or *Lonicera japonica* or both (see, e.g., abstract and entire translated document). The particular species names for the pumpkin seed and safflower used are given in paragraph [0015]. The composition can also be a health food (paragraph [0021]). While Yoshida does not teach that this composition is a follicle-stimulating hormone agent, it is described in paragraph [0015] that the flowers of *Carthamus tinctorius* are used for the treatment of women's diseases, specifically menopause (climacteric disturbance), which is one of the instantly claimed uses.

As readily admitted by Applicant on page 3, lines 19-24 of the instant specification, Kojima et al. beneficially teach a composition comprising Cucurbita seed, Plantago and Lonicera and at least one additional crude drug such as safflower (see, e.g., claim 1 and entire document). The particular species of each of the above herbals are given respectively on column 2, line 33; column 3, line 13; column 2, line 40 and column 2, line 48. While Kojima does not teach that this composition is a follicle-stimulating hormone agent, it is noted that by Kojima et al. that safflower is used in the treatment of gynecological disorders and climacteric disturbance (column 3, lines 14-19), which is one of the instantly claimed uses.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a composition comprising *Cucurbita moschata*, *Carthamus tinctorius*, *Plantago Asiatica*, and *Lonicera japonica* for treating various health conditions. As safflower was well known in the art at the time of the invention as a treatment for menopause, it would have further been obvious to use this composition to treat menopause, and as menopause is known to be caused by a high level of follicle-stimulating hormone, it would be obvious to use this composition to treat any condition associated with high levels of follicle-stimulating hormone. The adjustment of particular conventional working conditions (e.g., determining a suitable effective dosage and/or formulation (i.e., tablet, powder, syrup or functional food) provided) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/553,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to a composition comprising *Cucurbita moschata*, *Carthamus tinctorius*, *Plantago Asiatica* and *Lonicera japonica*.

Claims 1-10 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-8 and 10-11 of copending Application No. 10/964,750. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to a composition comprising *Cucurbita moschata*, *Carthamus tinctorius*, *Plantago Asiatica* and *Lonicera japonica*.

Claims 1-10 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/547,548. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to a composition comprising *Cucurbita moschata*, *Carthamus tinctorius*, *Plantago Asiatica* and *Lonicera japonica*.

The above rejections are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather Anderson whose telephone number is (571) 270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry KcKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA

CHRISTOPHER R. TATE
PRIMARY EXAMINER